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EXAMINER

KRUER, KEVIN R

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/790,338
Filing Date: March 01, 2004
Appellant(s): LUTHRA ET AL.

Curtis B. Herbert
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 17, 2007 appealing from the Office action mailed May 3, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 54-104, 151-197, 199-206, and 209-215 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. There is no explicit support of the limitation "free of covalent crosslinks." Furthermore, there is no evidence to show such a teaching is inherent. To establish inherency, the extrinsic evidence must make clear that the missing descriptive

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matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. The limitation is understood not to be inherent to the inventive examples in the specification for the reasons stated in the previous action.

Furthermore, claims 167, 170-189, and 206 are rejected under 35 U.S.C. 12, first paragraph because the original disclosure does not contain support for the endpoint "26 degree Centigrade."

2. Claims 54-104, 151-197, 199-206, and 209-215 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the skilled artisan would go about distinguishing "covalent crosslinks" from ionic crosslinks since virtually every bond has some ionic and some covalent characteristics.

(10) Response to Argument

GROUPING OF CLAIMS

Appellant's grouping of claims is for argument purposes only. The groupings are not understood to be an attempt to get said groupings to "stand or fall together."

Rather, the groupings are understood to be a means for appellant to conveniently refer to a group of claims in short hand.

LEGAL AUTHORITY

Appellant's summary of the current state of the law with respect to the Written Description Requirement and Indefiniteness is acknowledged. Since said section does not directly address the issues before the Board for appeal, the examiner will reserve comment with regard to whether the summary is a full and accurate synopsis of the current state of the law.

ANALYSIS

I. Rejection Under 35 U.S.C. 112, first paragraph

A. The rejection of claims of Groups 1, 2, and 3 for lack of written description for the term "free of covalent crosslinks" fails because this limitation is explicitly supported in the specification and because the Office Action's prima facie case of rejection used the wrong legal standard

The header states the term "free of covalent crosslinks" is "explicitly supported" in the specification. Appellant fails to provide a citation which explicitly supports said language. Since the term is not explicitly supported by the specification, a prima facie case of rejection is considered to be sufficiently established. To rectify the lack of explicit support for said term, Appellant attempts to establish the term "free of covalent crosslinks" is an inherent property of the claimed invention.

Specifically, appellant argues that the term "free of covalent crosslinks" is inherent to the claimed invention because "a copolymer in a coating would normally be considered to be free of covalent crosslinks unless it is taught as being crosslinked." Said argument is not persuasive because assumptions cannot rise to the level of inherency. For a property to be inherent it must necessarily be present-the mere

possibility that it may be present is insufficient to establish inherency. Furthermore, it is noted that "free of covalent crosslinks" is a negative limitation. As noted in MPEP 2173.05(i), the mere absence of a positive recitation is not basis for exclusion.

Appellant further attempts to establish inherency with regards to said term by pointing to examples 1-8 in the specification. The examiner takes the position said disclosure is insufficient to establish support for the term "free of covalent crosslinks." Specifically, the hydroxyl functional methacrylates utilized in examples 1-8 are capable of forming crosslinks with other functional groups in the polymer, with additives such as the therapeutic agent, or with an adjacent layer.

In addition to the arguments noted above, Appellant argues Examples 1-5 describe monomers with a single double bond and that it is a "foundational principle of polymer science" that such polymer will be free of crosslinks via the reaction of two monomers consisting of a single double bond to make a linear chain. Appellant provides no evidence to support the conclusion that it is a "foundational principle of polymer science" that monomers consisting of a single double bond will be free of chemical crosslinks. Furthermore, the prior art of record in this application (US 6,530,950) refutes such a conclusion. Specifically, said reference teaches as crosslinked polymer that was made by reacting monomers consisting of a single double bond (acrylic monomers). Appellant fails to acknowledge that monomers consisting of a single double bond may comprise other functionalities that are capable of crosslinking. Such reactive functionalities include hydroxyl groups such as those that are present in the monomers of examples 1-5.

Appellant seems to agree with the examiner's conclusion that said functionalities are capable of crosslinking but argues "the potential of the copolymer to make covalent crosslink does not contradict the claimed "free of covalent crosslinks." The examiner agrees that said two groups are not mutually exclusive. However, the fact that all of appellant's examples have the potential to crosslink further supports the examiner's position that the term "free of covalent crosslinking" is not inherent to the claimed invention. If a composition is capable of crosslinking, it clearly is NOT inherently "free of covalent crosslinks." Since appellant has the burden of refuting the examiner's prima facie showing and has failed to do so, the examiner maintains the position that the term "free of covalent crosslinks" is new matter properly rejected under 35 U.S.C. 112, first paragraph.

In arguendo, if the Board finds that examples 1-5 support appellant's position, then the examiner takes the position that said showing is not commensurate with the claimed invention. Specifically, said showing would be to a very narrow class of addition polymers whereas the independent claims are directed to any copolymer (addition polymers or otherwise) meeting the claimed glass transition limitations.

Appellant further argues that the Patent Office's suggestion that the claimed limitation must be inherently supported is not correct. Rather, the claim limitation must be supported in the specification through express, implicit, or inherent disclosure (MPEP 2163). The examiner agrees that the support may be express, implicit, or inherent. However, as noted above, the term is neither expressly nor inherently disclosed. With regards to implicit disclosure, it is noted in MPEP 2173.05(i) the mere absence of a

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positive recitation is not basis for exclusion. Appellant fails to further explain how the term is “implicitly” supported. Therefore, the position is maintained.

B. The rejection of claims of Groups 2 and 3 for lack of written description for the term “26 degrees Centigrade” fails because (1) this limitation is explicitly supported in the specification and (2) the written description requirement is not an adequate basis to deny the applicant the right to amend a range in light of the prior art.

1. The claimed range of between 26 and about 40 degrees Centigrade is explicitly and implicitly supported in the application

Appellant fails to provide a citation where the endpoint “26 degrees Centigrade” is explicitly supported.

According to Appellant, the specification teaches the copolymers should have a T_g close to a physiological temperature (page 12, lines 7-9) which is understood to be around 37°C (page 5, line 21 to page 6, line 2). Appellant argues the claimed range is supported because it is understood by ordinary artisans to be approaching a “physiological temperature.” Said argument is not persuasive. Appellant has provided no evidence to support the conclusion that the range 26-40°C would be understood by the skilled artisan to be a physiological temperature. Furthermore, it would seem farfetched for a skilled artisan to conclude that 26°C (78.8°F) is a “physiological temperature” since death is a virtual certainty at or near that temperature.

Appellant further argues that the application discloses the role of the T_g with respect to release of therapeutic agent, which appellant concludes can be reasonably read with wide scope, with something between room temperature and somewhat over

physiological temperature being a reasonable range. Again, appellant provides no evidentiary support to buttress the conclusory statements. The original disclosure never discusses "room temperature" and appellant provides no explanation as to why "room temperature" is implicitly or inherently disclosed.

Secondly, Appellant argues the application states the "weighted Tg averages for copolymers and polymers are set forth herein include from0-40C." Appellant argues the skilled artisan would appreciate that all ranges and values within these explicitly stated ranges are contemplated. Said position is not persuasive because it is inconsistent with the current state of the law.

2. The written description requirement is not an adequate basis to deny the applicant the right to amend a range in light of the prior art; case law plainly states that the applicant has the opportunity to make such amendments

Appellant argues that the Patent Office has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Said burden has been met. Specifically, the examiner has noted that the endpoint is not explicitly supported in the specification. Furthermore, the examiner has found no evidence said endpoint is inherently supported in the specification. Appellant argues that the broad disclosure of 0-4⁰0C should be understood to implicitly support the endpoint 26⁰C, but said position is not consistent with the current state of the law.

II. REJECTION UNDER 35 U.S.C. 112, SECOND PARAGRAPH

Appellant argues the examiner's position is a "naked assertion...without reference to any authority or form of evidence and fails to establish a prima facie case for the rejection." Specifically, appellant argues that the terms "covalent" and "ionic" are commonly used to distinguish different types of bonds and that the skilled artisan would readily distinguish covalent bonds from ionic bonds. Furthermore, appellant argues said terms are defined in various dictionaries, such as the American Heritage Dictionary. Appellant further argues that some degree of commonality would not prevent artisans from distinguishing covalent bonds from ionic bonds in the context of the claims. Said arguments have been fully considered but are not persuasive. Most bonds are neither fully ionic nor fully covalent, but have characteristics of both kinds of bonds. Appellant takes the position that the examples support the absence of one type of crosslink (covalent) but not necessarily ionic crosslinks. However, Appellant gives no guidance to the skilled artisan how to distinguish between these two types of crosslinks. Furthermore, the claims cover a wide class of copolymers and it is not clear from the disclosure that the determination of constitutes an ionic versus a covalent crosslink is based upon the same criteria regardless of the chemistry involved. If there is a universal criteria, appellant has failed to identify it.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Kevin R Kruer/

Primary Examiner, Art Unit 1794

Conferees:

/Rena L. Dye/

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/Carol Chaney/

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